REMARKS

Claims 1-19, 21-25 and 28-36 are pending, wherein claims 1, 14, 15, 18, 23-25, 30, 31 and 36 have been amended and claims 20, 26 and 27 were cancelled. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

The claims are generally directed to methods for treating disordered tissue caused by at least one of a virus, bacteria, or a fungus that include applying an anti-infective composition to the disordered tissue in a manner that causes the anti-infective composition to penetrate into the disordered tissue. In the embodiment of claim 14, penetration is enhanced by omitting certain materials (*i.e.*, menthol, thymol, eucalyptol, eugenol, camphor, hexetidine, and anethol) that can inhibit rapid and effective penetration of the anti-infective composition into the disordered tissue (*e.g.*, by actually retarding penetration or enhancing the skin's natural resistance to penetration). Application, p. 7, ll. 1-12. These materials are used in formulating topical treatment compositions according to U.S. 5,753,270 to Beauchamp et al. Examples 1-6 each utilize a composition that includes significant quantities of menthol, thymol and eucalyptol. Col. 5, l. 40 – col. 6, l. 38. Elsewhere Beauchamp discloses the use of one or more of menthol, thymol, eucalyptol, eugenol, camphor, hexetidine, and anethol as the required antiseptic, anesthetic, terpene and/or alcohol. Col. 4, ll. 34-57; col. 5, ll. 27-28. Beauchamp does not teach or suggest a topical treatment composition that is substantially free of menthol, thymol, eucalyptol, eugenol, camphor, hexetidine, and anethol. Claim 14 as amended is neither anticipated by nor obvious over the teachings of Beauchamp, either alone or in combination with any other art of record.

Moreover, Beauchamp explicitly teaches the necessity of applying the disclosed topical treatment composition "to the afflicted area 3 to 4 times over a one minute period", followed by "[r]epeat[ing] every 3 minutes over a 10 minute period", followed by "[r]epeat[ing the] procedure after approximately ½ to 1 hour", followed by "[r]epeat[ing] application ... every 2 to 3 hours or until activity is stopped and healing is evident". Col. 5, ll. 55-64. In contrast, the treatment composition and methods as described in the Application do not require such frequent re-application. In fact, the Application implies that a single application in which the composition forms a reservoir of anti-infective composition within the disordered tissue may be sufficient to complete treatment. *See* App., p. 19, ll. 10-20; Example 6. Compared with the requirement in Beauchamp that the Beauchamp composition be applied over and over to obtain relief, the ability to complete the treatment in a single application (or else a small number of infrequent

applications) is a surprising and unexpected result. That is further evidence of the patentability of claim 14.

Claims 1-13, 15-19 and 21-24 depend from claim 14 and are likewise patentable over the art of record. Moreover, they contain additional limitations that further distinguish over the art or record. For example, claim 1 recites a method in which the organohalide comprises at least one quaternary ammonium halide compound having an ammonium nitrogen and an alkyl radical with six to eighteen carbons bonded to the ammonium nitrogen. *See* Application, p. 20, ll. 15-21. The only organohalide, quaternary ammonium, or benzalkonium compound disclosed in Beauchamp is "benzethonium chloride" (col. 4, ll. 37, 52, 58) , which does not have the chemical structure as required by claim 1 as amended. This is clear from the evidentiary document attached hereto as Exhibit A, entitled "Benzethonium chloride", Wikipedia (7/7/08). For this additional reason, claim 1 is believed to be patentable over Beauchamp, either alone or in combination with any other art of record. Similar arguments apply to claims 3 and 15, which are not met by the benzethonium chloride compound of Beauchamp.

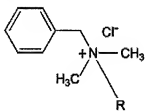
Claim 10 further specifies that the "treatment composition is substantially oil free". App., p. 33, ll. 8-16. In contrast, Beauchamp discloses compositions that include oils such as menthol, thymol and eucalyptol in a combined concentration of about 2.5% by weight. Col. 4, ll. 34-57; col. 5, ll. 44-46. For this additional reason, claim 10 is believed to be patentable over Beauchamp, either alone or in combination with any other art of record.

Claim 11 further specifies a ***method*** in which the "treatment composition is no longer visibly detectable on said disordered tissue within about two minutes after application of said treatment composition onto said disordered tissue". The Beauchamp composition includes oils such as menthol, thymol and eucalyptol that are non-volatile and would be expected to remain oily and visible on the skin surface two minutes after application of the Beauchamp composition. Apart from this, Beauchamp explicitly discloses a method in which the topical composition is re-applied numerous times every few minutes. Col. 5, ll. 55-64. The Beauchamp composition will therefore remain "visible" because it is repeatedly reapplied.

Claim 19 further specifies that the "treatment composition is substantially free of penetration inhibiting components" such as those included in Beauchamp (*see* App., p. 7, ll. 1-12), which may constitute the reason why the Beauchamp composition must be re-applied over and over in order to provide the desired relief.

Claims 23 and 24 recite application of the anti-infective to specific types of disordered tissues (*i.e.*, smallpox and anthrax, respectively) that are neither taught nor suggested in Beauchamp. Whether or not the Beauchamp composition might possibly provide relief to the symptoms relating to smallpox and anthrax is beside the point because Beauchamp does not teach or suggest treating such ailments. A new use for a known compound is patentable unless the specifically claimed use is either anticipated or obvious over the art of record. Moreover, it must be shown that there was a reasonable expectation of success at the time of the invention to support an allegation of obviousness. There is no evidence in the record to support any of the foregoing allegations. It would not be reasonable for one of ordinary skill in the art to expect a topical treatment composition used to treat relatively minor conditions such as cold sores and acne as in Beauchamp would be efficacious against an extremely virulent killer such as smallpox, which has historically caused pandemics and mass death, and/or anthrax. The highly penetrating nature and mode of application of the anti-infective compositions according to the claims is what makes them useful in treating smallpox and anthrax. This is in contrast to the relatively non-penetrating compositions of Beauchamp, which must be re-applied numerous times to have any medicinal effect according to Example 1 (col. 5, ll. 55-64).

Claim 25 alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising (1) identifying disordered tissue; (2) providing a treatment composition comprising at least one anti-infective agent in a carrier, the anti-infective agent comprising an organohalide, and wherein said treatment composition is a liquid comprising a tissue penetrating agent for penetrating skin, wherein said anti-infective agent comprises at least one benzalkonium chloride compound having the following chemical structure:



wherein R is an alkyl group having 8-18 carbons; and (3) applying the treatment composition to the disordered tissue by rubbing back and forth in an oscillating motion so as to cause or allow the treatment composition to form a reservoir within the disordered tissue in order for the

treatment composition to kill at least one of viruses, bacteria or fungus within the disordered tissue before diffusing beyond the disordered tissue. Support for the amendments to claim 25 is found in the Application at page 14, lines 18-19 and page 20, lines 15-21. Beauchamp neither teaches nor suggests the combination of limitations recited in claim 25.

First, Beauchamp neither teaches nor suggests a treatment composition that includes at least one benzalkonium chloride compound having the claimed chemical structure. Instead, the only quaternary ammonium antiseptic compound disclosed in Beauchamp is benzethonium chloride, which does not fall within the claimed chemical structure, as evidenced by Exhibit A hereto. The "R" in benzethonium chloride is not "an alkyl group having 8-18 carbons" but a diethyl ether moiety that is itself bonded to a substituted aromatic phenolic group.

Second, Beauchamp neither teaches nor suggests a treatment method in which the treatment composition is applied in the manner claimed (*i.e.*, by rubbing back and forth in an oscillating motion so as to cause or allow the treatment composition to form a reservoir within the disordered tissue). If Beauchamp taught such a method, rather than merely dabbing on the composition using a "cotton swab" (col. 6, line 10), it perhaps would not be necessary to constantly re-apply the composition as taught at col. 5, lines 56-64. Simple math shows that Beauchamp requires 9-12 applications during the first 10 minute treatment period according to step 1, repeating this 9-12 application treatment at least once within ½ to 1 hour according to step 2, which results in 18-24 applications, and then repeating the 9-12 application treatment every 2 to 3 hours until relieve is achieved, for a total of at least 27-36 applications at the very minimum and possible many more to effect treatment. In contrast, it is not necessary to repeat the treatment method of claim 25 numerous times (*i.e.*, 27-36 times *minimum* as in Beauchamp) to obtain relief. Instead, relief may be obtained by applying the composition once and perhaps twice (*see* App, p. 19, ll. 10-20), which results from the combination of the highly penetrating treatment composition coupled with the mode of application (*see* examples). That is a surprising and unexpected result compared to Beauchamp. In view of the foregoing, Applicants submit that claim 25 is neither anticipated by nor obvious over Beauchamp, either alone or in combination with any other art of record.

For example, the Office Action combines Beauchamp with Remington's Pharmaceutical Sciences, p. 685 in rejecting some of the claims. The problem with this combination is that Remington's does not disclose a method for enhancing localized *topical* treatment of a skin disorder. Rather, Remington's discloses a method of achieving ***systemic*** circulation of a drug

within a person by vigorously rubbing a drug into a person's hair follicles in a manner that causes the drug to penetrate through the skin and into the patient's "circulation". The quantity of benzethonium chloride component found in the Beauchamp composition (*i.e.*, 0.2%) is not suitable for ingestion and/or rapid diffusion into the bloodstream system because it is highly toxic. *See* Application, page 22, lines 9-11. Moreover, Beauchamp neither teaches nor suggests the desirability of applying the disclosed composition in a manner other than topically dabbing with a cotton swab a minimum of 27-36 times. If Beauchamp were attempting to achieve systemic treatment as in Remington's, Beauchamp would not have taught 27-36 topical applications over the first 3-4 hour period.

Beauchamp certainly does not suggest the desirability of applying the disclosed composition in a manner that would cause it to pass through the patient's skin and into the patient's "circulation", which is the desired result according to Remington's. One of skill in the art would not have been motivated to apply the topical treatment composition of Beauchamp with the systemic circulation introduction method of Remington's, as the result might be dangerous or even toxic to the patient (*i.e.*, the benzethonium chloride component found in the Beauchamp composition is not suitable for ingestion or systemic circulation because it is highly toxic). Accordingly, Applicant submits that it would be improper to combine Beauchamp with Remington's in the manner urged in the Office Action,

Moreover, even if one were to combine Beauchamp and Remington's, the resulting combination would not teach or suggest the combination of elements recited in claim 25 as amended. The purpose of the method taught under the heading "Topical Route" of Remington's is to achieve "systemic circulation to cause systemic effects." Remington's teaches that absorption through topical administration to achieve "*systemic effects*... is too erratic for the topical route to be used for systemic therapy. Recent work with aprotic solvent vehicles has, however, renewed interest in topical administration for *systemic effects*". To achieve better "systemic effects", Remington's discloses a method of vigorously rubbing a medicament over hair follicles, which forces the preparation into the hair follicles and glands. "Since much of a drug that is absorbed through the epidermis ***diffuses into the circulation without reaching a high concentration in some portions of the dermis***, systemic administration may be preferred in lieu of or in addition to topical administration." In view of the explicit teachings in Remington's, one of skill in the art would not reasonably expect the vigorous rubbing method of Remington's to "cause or allow the treatment composition to form a reservoir within the disordered

tissue" as required by claim 25. Instead, Remington's clearly teaches that composition "***diffuses into the circulation without reaching a high concentration in ... the dermis***" when employing the rubbing method disclosed therein. That does not describe forming a reservoir of treatment composition within the disordered tissue, as required by claim 25. Moreover, claim 25 claims a method for "*locally treating* pathogen-induced disordered tissue" while Remington's teaches rubbing to achieve "systemic circulation" of a drug. Accordingly, even if one were to combine Beauchamp, which only discloses topically dabbing with a cotton swab, with Remington's, which discloses rubbing to the point of achieving "systemic circulation", the combined teachings would not suggest the method of claim 25. Claims 28 and 29 depend from claim 25 and are likewise patentable.

Claim 30 alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising (1) identifying disordered tissue that comprises one or more lesions caused by at least one of a virus, a bacteria, or a fungus; (2) providing a treatment composition comprising at least one anti-infective agent in a carrier, the at least one anti-infective agent comprising an organohalide, and wherein the treatment composition comprises a tissue penetrating agent for penetrating skin; and (3) applying the treatment composition to the disordered tissue while *firmly compressing* the disordered tissue against at least one of bone, tooth, gum, or other tissue underlying the disordered tissue in order to assist penetration of the treatment composition into the disordered tissue. The combination of Beauchamp and Remington's does not disclose or suggest the combination of limitations recited in claim 30.

For example, neither Beauchamp nor Remington's discloses a method of applying a composition that includes "applying said treatment composition to said disordered tissue while ***firmly compressing*** said disordered tissue ***against at least one of bone, tooth, gum, or other tissue underlying said disordered tissue*** in order to assist penetration of said treatment composition into said disordered tissue". Beauchamp discloses applying the topical treatment composition a minimum of 27-36 times using a cotton swab. Col. 5, ll. 55-64; col. 6, l. 10. Nowhere does Beauchamp teach or suggest applying a treatment composition to disordered tissue while *firmly compressing* the disordered tissue against at least one of bone, tooth, gum, or other tissue underlying the disordered tissue for any reason whatsoever, let alone to assist penetration of the treatment composition into the disordered tissue. Remington's likewise fails

to teach or suggest this mode of applying a composition for any reason whatsoever, let alone "for locally treating ... disordered tissue" as recited in claim 30.

Dependent claims 31-35 are likewise patentable over the applied art and recite limitations that further distinguish over the art of record. For example, claim 31 recites a benzalkonium chloride compound having a chemical formula that is neither taught nor suggested by either Beauchamp or Remington's. Claim 35 further requires that the treatment composition be applied to the disordered tissue using a finger. Beauchamp discloses using a "cotton swab" to apply the disclosed composition but not a finger. Col. 6, l. 10. The statement in the Office Action that column 6 of Beauchamp discloses using a finger to apply the composition appears to be mistaken. No such teaching can be found there or anywhere else in Beauchamp. Applicant's representative performed a word search for "finger" in the version of Beauchamp on the official USPTO website but found no incidence of this word *anywhere* in Beauchamp.

Withdrawn claim 36 is suitable for rejoinder upon the allowance of claim 30 from which it now depends.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 14th day of July 2008.

Respectfully submitted,

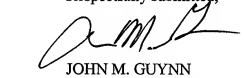


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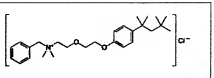
EXHIBIT A

Benzethonium chloride

From Wikipedia, the free encyclopedia

Benzethonium chloride is a synthetic quaternary ammonium, surfactant, antiseptic, and anti-infective compound used as a topical antimicrobial agent in cosmetics and personal care products like anti-itch ointments and antibacterial moist towelettes and wipes. Benzothonium chloride is also used is the food industry as a disinfectant and preservative. [1]. It has the appearance of an odorless white crystalline hygroscopic powder and has a melting point of 162-164 °C. The compound is moderately soluble in water and is toxic orally because it may cause failure in neuromuscular transmission as a result of pathological disturbance at the myoneural junction.[2]

It is available under trade names **salanine, BZT, diapp, quatrachlor, polymine d, phemithyn, antiseptol, disilyn, phermerol**, and others. [3]



Benzethonium chloride

Systematic (IUPAC) name

benzyl-dimethyl-[2-[2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethoxy]ethyl] azanium chloride

Identifiers	
CAS number	121-54-0
ATC code	D08AJ58
PubChem	8478
Chemical data	
Formula	$C_{27}H_{42}ClNO_2$
Mol. mass	448.081 g/mol
SMILES	eMolecules & PubChem
Pharmacokinetic data	
Bioavailability	?
Metabolism	?
Half life	?
Excretion	?
Therapeutic considerations	
Pregnancy cat.	?
Legal status	OTC(US)
Routes	Topical

Retrieved from "http://en.wikipedia.org/wiki/Benzethonium_chloride"
Categories: Chlorides | Quaternary ammonium compounds | Surfactants | Antiseptics | Disinfectants | Preservatives
Hidden categories: Pharmacology articles needing expert attention | Articles needing expert attention | Pages needing expert attention